

Jeb Bush  
Governor

# Department of Environmental Protection

Marjory Stoneman Douglas Building  
3900 Commonwealth Boulevard  
Tallahassee, Florida 32399-3000

'99 APR 22 A9:28

David B. Struhs  
Secretary

April 19, 1999

Dockets management Branch (HFA-305)  
U.S. Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20852

Docket No. 98P-0504 "Performance Standard for *Vibrio vulnificus*; Request for Comments"

To Whom It May Concern:

This letter is in opposition to the petition by CSPI for the establishment of *Vibrio vulnificus* performance standards. The opposition is based on two points. First, the U.S. Food and Drug Administration has signed an MOU with the Interstate Shellfish Sanitation Conference which acknowledges the ISSC as the primary voluntary national organization of state shellfish regulatory officials to provide guidance and counsel on matters for the sanitary control of shellfish. The ISSC has dealt with *Vibrio vulnificus* in shellfish through the deliberative issue process, choosing to use education and warning labeling in addition to harvesting time restrictions during warmer months of the year in those states where illnesses have been implicated. Since the ISSC has implemented controls, the U.S. FDA should reject this petition. Second, while a small number of illnesses and deaths occur each year from the consumption of raw shellfish, the number of illnesses per meals served is close to 1 in a million. Risk management specialists indicate that this level of risk is equal to no risk at all. Thus the overreaction of requiring all processors in the Gulf of Mexico to "cook" shellfish to prevent illness is unnecessary. FDA should reject this petition.

Sincerely,

DIVISION OF MARINE RESOURCES

Mark L. Collins

Environmental Administrator

Bureau of Marine Resource Regulation and  
Development

MC/mc

98P-0504

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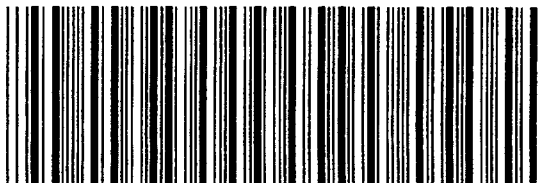
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